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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

Application Number. : 09/237,605

Appellant : Richard J. Lazzara et al.
Filed : January 25, 1999
Title : Infection-Blocking Dental Implant
TC/A.U. : 3738
Examiner : Paul Prebilic

Docket Number : 247168-000035USC1

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

Dear Sir:

This Appeal Brief relates to U.S. Serial No. 09/237,605 (application as originally filed on January 25, 1999, attached as Ex. 1) and is filed pursuant to Appellant's appeal to the Board of Patent Appeals and Interferences from the rejection of claims 51 and 60-75 in the Final Office Action dated October 21, 2008 (Ex. 2). A Notice of Appeal was filed on February 23, 2009 (Ex. 3).

The due date for this Appeal Brief is two months from the Notice of Appeal filing date, which is April 23, 2009. This Appeal Brief is being filed with a one-month extension of time, thereby extending the due date to May 23, 2009.

I. REAL PARTY IN INTEREST

The real party in interest is Biomet *3i*, LLC, a corporation organized and existing under the laws of the State of Florida, having a place of business at 4555 Riverside Drive, Palm Beach Gardens, Florida 33410.

II. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences that will directly affect, be directly affected by, or have a bearing on the Board of Patent Appeals and Interferences in the present appeal.

III. STATUS OF CLAIMS

Claims 1-50 and 52-59 were previously cancelled.

No claims have been allowed.

Claims 51 and 60-75 as filed on January 11, 2008 in the Amendment with RCE (Ex. 4) are currently pending and finally rejected in the above-referenced application. It is from the final rejection of claims 51 and 60-75 that this appeal is taken. Independent claims 51 (and its dependent claims 60-62), 63 (and its dependent claims 64-67), and 68 (and its dependent claims 69-75) stand rejected under 35 U.S.C. § 103 as being obvious over JP 3-146679 to Haruyuki et al., which has an English translation (“Haruyuki”) (Ex. 5) or Journal article titled “Design and Surface Characteristics of 13 Commercially Available Oral Implant Systems” by Wennerberg et al. (“Wennerberg”) (Ex. 6) in view of U.S. Patent No. 5,571,017 to Niznick et al. (“Niznick”) (Ex. 7).

IV. STATUS OF AMENDMENTS

No amendments were filed subsequent to the Final Office Action Dated October 21, 2008
(Ex. 2).

V. SUMMARY OF CLAIMED SUBJECT MATTER

Pursuant to 37 C.F.R. § 41.37(c)(1)(v), exemplary references to the specification by page and line number and to the drawings and reference characters are included in the below summary of the independent claims. Such references are by way of example only and are not to be construed in a limiting manner.

Reference will be made herein to Appellants' application as originally filed on January 25, 1999 (Ex. 1).

Claims 51, 63, and 68 are the independent claims within the pending claim set. All of the independent claims relate to a dental implant 10 that has a head portion 12 that receives a dental restoration component. Ex. 1, page 1, lines 12-13, page 4, lines 30-31. Each dental implant 10 has a lowermost end opposing the head portion 12 and a threaded portion. Ex. 1, FIG. 1. Other features of each of the independent claims are summarized below.

Independent Claim 51

As claimed by independent claim 51, a dental implant made of titanium metal is disclosed. Ex. 1, e.g., FIG. 1. The dental implant includes a smooth head portion 12 for receiving a dental restoration component. Ex. 1, page 1, lines 12-13, page 4, lines 2-4, 30-31. The dental implant further includes a lowermost end opposing the head portion and a threaded portion for engaging bone between said head portion and said lowermost end. Ex. 1, e.g., FIG. 1. The dental implant further includes a roughened region 18 for facilitating osseointegration with bone located on the threaded portion and extending to the lowermost end of the implant 10. Ex. 1, FIG. 1, page 4, lines 1-2. The roughened region 18 is uniformly acid-etched with a second acid solution (Ex. 1, page 7, lines 19-23) after a native oxide layer has been removed by contact with a first acid solution (Ex. 1, page 6, lines 8-10, page 7, lines 11-12) with minimum

consumption of titanium metal (Ex. 1, page 6, lines 23-25). The roughened region includes an array of irregularities having peak-to-valley heights not greater than about 10 microns. Ex. 1, page 8, lines 22-23.

Independent Claim 63

As claimed by independent claim 63, a titanium dental implant is disclosed. Ex. 1, e.g., FIG. 1. The dental implant includes a head portion 12 that includes a non-rotational feature 17 (Ex. 1, FIGs. 1, 2) for engaging a dental restoration component (Ex. 1, page 4, lines 30-31) and a smooth machined surface (Ex. 1, page 3, lines 32-40, page 4, line 4). The dental implant further includes a lowermost end opposing the head portion. Ex. 1, e.g., FIG. 1. The threaded portion has continuous thread turns, is located between the head portion and the lowermost end, and includes a self-tapping region adjacent to the lowermost end. Ex. 1, FIG. 1. The threaded portion has an acid-etched surface (Ex. 1, page 7, lines 19-23) for facilitating osseointegration with said bone (Ex. 1, page 4, lines 1-2). The acid-etched surface extends to the lowermost end of the implant 10 and within the self-tapping region. Ex. 1, FIG. 1. The acid-etched surface is produced on the threaded portion after a native oxide layer has been removed from the threaded surface. Ex. 1, page 6, lines 1-2. The acid-etched surface has an array of irregularities having peak-to-valley heights not greater than about 10 microns. Ex. 1, page 8, lines 22-23. The irregularities include cone-shaped elements. Ex. 1, page 8, lines 23-25.

Independent Claim 68

As claimed by independent claim 68, a titanium dental implant is disclosed. Ex. 1, e.g., FIG. 1. The dental implant includes a head portion 12 for receiving a dental restoration component (Ex. 1, page 4, lines 30-31) that includes a non-rotational feature 17 (Ex. 1, FIGs. 1, 2) for engaging the dental restoration component. The dental implant further includes a

lowermost end opposing the head portion. Ex. 1, FIG. 1. The dental implant further includes a threaded portion having continuous thread turns located between the head portion and the lowermost end. Ex. 1, FIG. 1. The threaded portion includes a cylindrical section and a tapered section immediately adjacent to the lowermost end. Ex. 1, FIGs. 1, 2. The cylindrical section is longer than the tapered section. Ex. 1, FIG. 1. The tapered section includes a self-tapping region that extends to the lowermost end. Ex. 1, FIG. 1. The threaded portion has an acid-etched surface (Ex. 1, page 7, lines 19-23) for facilitating osseointegration with bone (Ex. 1, page 4, lines 1-2). The acid-etched surface extends from the lowermost end and into the cylindrical section of the threaded portion (Ex. 1, FIG. 1) and is produced on the threaded portion after a native oxide layer has been removed (Ex. 1, page 7, lines 11-12). The acid-etched surface has an array of irregularities having peak-to-valley heights not greater than about 10 microns. Ex. 1, page 8, lines 22-23. The irregularities include cone-shaped elements. Ex. 1, page 8, lines 23-25.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Whether claims 51 and 60-75 were improperly rejected under 35 U.S.C. § 103 as being obvious over Haruyuki (Ex. 5) or Wennerberg (Ex. 6) in view of Niznick (Ex. 7)?

VII. ARGUMENT

Before discussing the three grounds of rejection to be reviewed on appeal, Appellant will first discuss the general law of obviousness.

The Supreme Court in KSR Int'l Co. v. Teleflex Inc., 127 S. Ct. 1727, 82 U.S.P.Q.2d 1385 (2007) stated that the teaching, suggestion, and motivation test is not to be rigidly applied, but did not apply a specific test to determine obviousness. Applying the KSR Int'l decision, the Federal Circuit in Leapfrog Enterprises, Inc. v. Fisher-Price, Inc. stated that “[a]n obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of a case.” Leapfrog, 485 F.3d 1157, 1161, 82 U.S.P.Q.2d 1687, 1690 (Fed. Cir. 2007). Indeed, the common sense of those skilled in the art demonstrates why some combinations would have been obvious where others would not. See KSR Int'l, 127 S. Ct. at 1741-43, 82 U.S.P.Q.2d at 1390-91.

Care must still be extended “not to allow hindsight reconstruction of references to reach the claimed invention without any explanation as to how or why the references would be combined to produce the claimed invention.” Innogenetics N.V. v. Abbott Labs., 512 F.3d 1363, 1374, 85 U.S.P.Q.2d 1641, 1648 n.3 (Fed. Cir. 2008). As “the Supreme Court suggests, a flexible approach” to the teaching, suggestion, or motivation to combine test “prevents hindsight” reconstruction. In re Translogic Tech. Inc., 504 F.3d 1249, 1260, 84 U.S.P.Q.2d 1929, 1937 (Fed. Cir. 2007) (citing In re Rouffet, 149 F.3d 1350, 1357, 47 U.S.P.Q.2d 1453, 1458 (Fed. Cir. 1998)). In making an obviousness determination, it “can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” See KSR Int'l, 127 S. Ct. at 1741, 82 U.S.P.Q.2d at 1390-91.

“[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” Id., 127 S. Ct. at 1740-41, 82 U.S.P.Q.2d at 1396 (citing In re Kahn, 441 F.3d 977, 988, 78 U.S.P.Q.2d 1329, 1336 (Fed. Cir. 2006)); see also Ex parte Smith, 83 U.S.P.Q.2d 1509, 1515 (Bd. Pat. App. & Int. 2007). The mere fact that references can be combined or modified does not itself render the resultant combination obvious. A central principle in the obviousness inquiry is “whether the improvement is more than the predictable use of prior art elements according to their established functions.” KSR Int’l, 127 S. Ct. at 1740, 82 U.S.P.Q.2d at 1396.

The Examiner, of course, has the initial burden of establishing a prima facie basis to deny patentability to a claimed invention under any statutory provision. In re Mayne, 104 F.3d 1339, 1341, 41 U.S.P.Q.2d 1451, 1453 (Fed. Cir. 1997).

For at least the reasons stated below, the Appellants respectfully submit that the Examiner has not set forth a prima facie case of obviousness under 35 U.S.C. § 103 and request reversal of the Examiner’s 35 U.S.C. § 103 rejection.

A. Claims 51 and 60-75 Were Improperly Rejected Under 35 U.S.C. § 103 as Being Obvious Over Haruyuki (Ex. 5) or Wennerberg (Ex. 6) in View of Niznick (Ex. 7).

As provided in more detail below, claims 51 and 60-75 are not obvious over the applied references for at least the following reasons:

- Haruyuki’s surface is not “inherently” the same as Appellants’ surface and cannot be duplicated;
- Wennerberg does not disclose acid-etched surfaces;

- the applied references and combination thereof do not result in the inventions of claims 51 and 60-62;
- the inventions of claims 63-67 are not obvious over the applied references;
- the inventions of claims 68-75 are not obvious over the applied references;
- the applied references and combination thereof do not result in the inventions of dependent claims 61, 67, and 72; and
- Dr. Porter's declaration establishes secondary evidence of non-obviousness.

1. Haruyuki's Surface Is Not "Inherently" the Same as Appellants' Surface and Cannot Be Duplicated

The Examiner contends that "since a similar type of etching process is used" in Haruyuki, Haruyuki's surface would "inherently" be the same as the Appellants' surface. Ex. 2, page 3. If the Examiner is correct in citing Haruyuki for producing a similar surface from a similar process, then it should be evident that the surfaces are, in fact, similar. Based on the Appellants' significant testing set forth in a Declaration under 37 C.F.R. § 1.132 by Dr. Prabhu Gubbi (the "Gubbi Declaration") (Ex. 8), submitted on June 26, 2003, the Appellants respectfully submit that (i) Haruyuki's roughened surface does not "inherently" correspond to the Appellants' surface and (ii) Haruyuki's surface cannot be duplicated.

Regarding Haruyuki, the English translation teaches a method of treating the surface of a titanium implant with a solution of hydrofluoric acid, which is then followed by post-treatment with a solution of hydrofluoric acid and hydrogen peroxide. Ex. 5, page 3, column 2. The initial treatment with a solution of hydrofluoric acid is said to create pits which have sharp edges and sharp spines. *Id.*, page 4, column 1. Then, the post-treatment with the solution of hydrofluoric acid and hydrogen peroxide is performed to smoothen the sharp edges and sharp spines, which may cause tissue irritation. *Id.*, page 4, column 2. Thus, Haruyuki does not teach a second

treatment that roughens the surface from which the native oxide had been removed. Haruyuki teaches a post-treatment used to smoothen the sharp edges and sharp spines produced by the first treatment, rather than to further roughen the surface, as required by the present claims. Id.

Thus, the Appellants respectfully disagree with the Office Action's statements that "Haruyuki does not teach smoothening the surface" and "[s]moothness' is not explicitly discussed." Ex. 2, p. 4, 5. Smoothness is, in fact, explicitly discussed at page 4, column 2 of the English translation of Haruyuki, which states, "Dipping in a mixed aqueous solution of HF and H₂O₂ in the posttreatment functions to smooth the sharp edges and sharp spines that appear at the microscopic depressions produced during the pretreatment" (emphasis added). Ex. 5, page 4, column 2.

Additionally, from Haruyuki's photographs, it is clear that the surfaces have a topography different from the Appellants' surface, perhaps due to the fact that the Appellants further roughen the surface after the native oxide is removed, while Haruyuki smoothen the surface created by the first step. To further compare Haruyuki's results with the Appellants' results, the Appellants have conducted several experiments. The results were reported in the Gubbi Declaration (Ex. 8). The Appellants' surface (i.e., the Osseotite® surface) is shown in Exhibit A of the Gubbi Declaration. Id. The results of repeating Haruyuki's experiments are reported in Exhibit B of the Gubbi Declaration.¹ Id. It is clear from the photomicrographs presented in Exhibit A of the Gubbi Declaration that the Appellants' Osseotite® surface is not obtained when the methods of Haruyuki's examples, shown in Exhibit B of the Gubbi Declaration, are repeated. Id. Furthermore, Haruyuki's photographs in Exhibit B do not resemble the surface achieved

¹ Exhibits C and D to Dr. Gubbi's Declaration relate to tests showing results of acid-etching with various mineral acids, and tests showing results of grit-blasting plus various acid-etching steps, respectively.

when Haruyuki's tests were repeated by Dr. Gubbi, which leaves the Appellants questioning Haruyuki's methodology. See id.

While the Board is encouraged to review the results of Dr. Gubbi's extensive Declaration in detail, for the Board's convenience, a one-page comparison including selected photographs from the Gubbi Declaration is included as Exhibit 9. The Appellants note that, in response to the Examiner's comment in the Final Office Action that "the photographs [of the one-page comparison] are of poor quality such that little detail can be ascertained therefrom", Exhibit 9 has been recreated. See Ex. 2, page 4. The same photographs and data were used to recreate the one-page comparison, and, thus, no new matter is being added. The purpose of this one-page comparison in Exhibit 9 is to easily compare (i) the surface that Haruyuki illustrated in Haruyuki's Japanese patent application as the desired surface (Ex. 8, Ex. B, Example 2), (ii) the surface that resulted from Dr. Gubbi's attempt to replicate Haruyuki's process, and (iii) the commercial Osseotite® surface according to the claimed invention.

In Exhibit 9, the first row shows the surface after Haruyuki's first step (see Ex. 5, FIG. 2) in which a titanium surface is treated with 4 % HF for 1 minute, creating a rough surface. Haruyuki's FIG. 4 shows a surface after two steps, including Haruyuki's "post-treatment" with 4% HF and 8% H₂O₂ for 15 seconds. See Ex. 5, FIG. 4. Haruyuki's FIGs. 2 and 4 appear to be similar, as might be expected, since Haruyuki teaches that the second treatment was only to "smoothen" the sharp edges and sharp spines created in his first treatment.

In the second row of Exhibit 9, the attempt to duplicate Haruyuki's process are shown. These results are taken from Exhibit B of Dr. Gubbi's Declaration (Ex. 8). Clearly, the process set forth in Haruyuki could not be repeated to produce the results that Haruyuki allegedly obtained.

In the third row of Exhibit 9, a surface according to the Appellants' invention is disclosed after the first step of removing the native oxide layer by contact with a first acid solution (immersing the implant in 8.45 wt% HF for 60 seconds) and after the second step of uniformly acid etching the implant (immersing the implant in a mixture of one part by volume of 37 wt% HCl and 7.4 parts by volume of 84.5% H₂SO₄ for 7 minutes at 60-70°C). Ex. 8, ¶E. The first step produces a relatively smooth surface. The second step produces a roughened surface.

Accordingly, in addition to the fact that Haruyuki discloses a process that could not be repeated by a skilled artisan (Dr. Gubbi), the surfaces disclosed by Haruyuki are different from the claimed surfaces. Thus, the Appellants disagree with the Examiner's statement that "the surface disclosed by Haruyuki falls within the claim scope" of the present claims. See Ex. 2, page 4. Furthermore, the Appellants submit that the extensive testing that they have done completely disproves the Examiner's position that if "a similar type of etching process is used [by Haruyuki] to form irregularities on the surface of the same material as claimed", then "the surface irregularities of Haruyuki . . . would inherently be the substantially the same as those set forth claims." Id., page 3.

2. Wennerberg Does Not Disclose Acid-Etched Surfaces

The Examiner has applied Wennerberg as disclosing titanium implant surfaces having a roughness under 10 microns. Ex. B, page 2. Specifically, the Examiner cites the 3i Miniplant® implant system and the Nobelpharma implant system. Ex. 2, page 2 (citing Ex. 6, page 623, column 2, paragraph 5, page 624, Table 1). The Appellants note that the 3i Miniplant® implant system was sold by the assignee of the present application.

Wennerberg studied the surface topography of thirteen commercially available oral endosseous implant systems, which it divided into four groups. Ex. 6, page 622. These groups

included: Group A (hydroxyapatite-coated implants), Group B (a titanium plasma-sprayed implant), Group C (titanium alloy implants), and Group D (commercially pure titanium implants). Id. at pages 622-623. The 3i Miniplant® and Nobelpharma implant systems relied upon by the Examiner are members of Groups C and D, respectively. See id. at page 624.

No reference to acid-etching whatsoever is made in Wennerberg. Furthermore, both the 3i Miniplant® system and the Nobelpharma system have machined surfaces. This is evidenced by Figs. 10 and 12 of Wennerberg, which show the surface patterns of the 3i Miniplant® and the Nobelpharma systems having machining lines. Ex. 8, page 630, 631. Moreover, Wennerberg states that the small differences in the surface topographies of the commercially pure titanium implants “may be explained by different manufacturing protocols and varying sharpness of the cutting tools.” Ex. 8, page 632 (emphasis added).

Further still, Niznick, which was filed at around the same time that Wennerberg was published states:

Some self-tapping screw implants are sold with a **machined surface**
(Nobelpharma and Implant Innovations, Inc. implants)

Ex. 7, col. 2, ll. 13-15 (emphasis added). This is further evidence that the 3i Miniplant® and Nobelpharma implant systems in Wennerberg that were relied upon by the Examiner did not include acid-etched surfaces, as in the present claims.

Furthermore, no where does Wennerberg disclose, teach, or suggest a threaded portion having a roughened region having an acid etched surface produced after a native oxide layer has been removed from the threaded portion, as in the present claims.

Thus, the implant surfaces of Wennerberg are very different from the implants of the present invention. Furthermore, the combination of Wennerberg and Niznick fails for the reasons set forth below.

3. The Applied References and Combination Thereof Do Not Result in the Inventions of Claims 51 and 60-62

Independent claim 51 recites:

- a smooth head portion for receiving a dental restoration component;
- a roughened region located on said threaded portion and extending to said lowermost end of said implant; and
- the roughened surface is uniformly acid etched and characterized by having an array of irregularities having peak-to-valley heights not greater than about 10 microns.

In other words, claim 51 requires, below the smooth head portion, a uniformly acid-etched surface extending from the threaded portion all the way to the lowermost end, and that this uniformly acid-etched surface has an array of irregularities having peak-to-valley heights not greater than about 10 microns.

It appears that Haruyuki and Wennerberg were cited by the Examiner for allegedly having the acid-etched surfaces defined by claim 51. Ex. 2, page 2. As mentioned above, the Appellants dispute the Examiner's position. Niznick was cited for teaching different regions of roughness and the location for the different regions of roughness. Ex. 2, page 3. Yet, as discussed below, Niznick's teaching of where, and to what degree, to roughen the implant is substantially different from the invention of claims 51, 60, and 62. Niznick's teaching is also substantially different from Haruyuki's teaching, and the combination of Wennerberg and Niznick would not result in the present invention.

a. Niznick and Haruyuki Teach Away From Their Combination

The Examiner's remarks regarding this section suggest that a reference's disclosure is not limited to preferred embodiments and that alternative embodiments – even if less preferred – are considered to be taught by the reference. Ex. 2, page 5. The Appellants do not disagree with this

statement or the Examiner's reliance on MPEP § 2123(II) but, rather, submit that this section is not applicable here. As noted in detail below, Haruyuki does not teach etching an implant surface to a depth exceeding 5 microns as an alternative embodiment. Rather, Haruyuki teaches that doing so could lead to a potentially grave situation for the patient, including causing cancer. Likewise, Niznick does not teach average peak-to-valley distances of an implant surface texture below 25 microns as an alternative embodiment. Rather, Niznick teaches that the implant surface must be exceedingly rough, i.e., 25 microns or greater. See Ex. 7, column 7, lines 13-14.

First, Haruyuki is very specific about what type of surface he desires. After providing several different examples using modified process steps, Haruyuki concludes that the microscopic depressions should have an average depth of 0.5 to 5 microns. Ex. 5, page 4, column 1, lines 1-5. Haruyuki also explains his reasoning:

The bases for specifying an average depth in the range from 0.5 to 5 μm are as follows: the anchoring effect between the bone and biorepair member is low at an average depth below 0.5 μm ; an average depth in excess of 5 μm , although providing a high anchoring effect, tends to result in the appearance of sharp spines and sharp edges at the ridge lies between depressions, which can cause tissue irritation (possibly a trigger for cancer).

Ex. 5, page 4, column 1, lines 22-32 (emphasis added). In other words, Haruyuki's primary concern is that if the depth of the microscopic depressions on the implant's surface exceeds 5 microns, then there tends to be a detrimental effect, which can possibly lead to tissue irritation or even a far more grave situation for the patient – cancer. See id. Furthermore, Haruyuki tested various types of processes and discards several of them because they produced the “sharp edges” and “sharp spines,” which lead to the peak-to-valley height being greater than 5 microns and the associated detrimental effects. See, e.g., Ex. 5, pages 7-8. Thus, contrary to the Examiner's assertion that the Appellants “exaggerated the statements” of Haruyuki in their analysis, the

Appellants' analysis is actually based on the exact and "actual language of the references", which is directly quoted above. See Ex. 2, page 5 (emphasis added).

Compared to Haruyuki, Niznick teaches that the implant's surface should be exceedingly rough. In fact, Niznick teaches that the main portion of the implant's surface should be at least five times greater than the surface specified by Haruyuki. When describing the first embodiment of FIG. 1, Niznick states:

The darkened, external, threaded, middle region 14 is relatively rough, with the average peak-to-valley distance of the surface texture being 25 microns or greater which is at least 25% greater than the roughness of the uncoated self-tapping threads 8 at distal end or uncoated proximal end surfaces 2 and 3.

Ex. 7, column 7, lines 11-14 (emphasis added) And, when describing the only other illustrated embodiment, which is shown in FIG. 2, Niznick repeats the same teaching:

Implant 20 has a darkened, external, threaded, middle region 27 with a surface that is relatively rough, with the average peak-to-valley distance of the surface texture being 25 microns or greater which is at least 25% greater than the roughness of the uncoated self-tapping threads 21 at [the] distal end and relatively smooth uncoated proximal end 26.

Id., column 7, lines 42-47 (emphasis added).

Consequently, while Haruyuki teaches the skilled artisan to avoid surfaces where the peak-to-valley height of the surface texture is greater than 5 microns because of potential biological problems, such as cancer, Niznick teaches that same skilled artisan to employ a surface where the peak-to-valley height of the surface texture is 25 microns or greater. In fact, the exceedingly rough implant is Niznick's invention, as can be seen by reviewing Niznick's claim 1. Ex. 7, column 7, line 67 – column 8, line 12. Thus, the Appellants do not base their teaching away argument solely on "[t]he fact that Niznick teaches that certain areas of the implant are relatively rough." See Ex. 2, page 5. Rather, the Appellants focus this argument on

the combination of Niznick's teaching of an exceedingly rough surface (i.e., greater than 25 microns) and Haruyuki's teaching that a roughness greater than even 5 microns can have serious detrimental effects. See Ex. 7, column 7, lines 42-47; see also Ex. 5, page 4, column 1, lines 22-32. Accordingly, the Appellants clearly are not showing nonobviousness "by attacking the references individually", as alleged by the Examiner. Rather, the Appellants are repeatedly emphasizing the problems with combining the references. See Ex. B, page 6.

The Examiner also relies on MPEP § 2123(II) in attempt to address the Appellants' position that Niznick and Haruyuki teach away from their combination. Ex. 2, page 5. MPEP § 2123(II) is titled "Nonpreferred and Alternative Embodiments Constitute Prior Art." This section, however, applies to Appellants' position that a reference teaches away from the invention itself (as the Appellants argue in a separate position detailed below), not that a reference teaches away from its combination with another reference. MPEP § 2123 states, "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." MPEP § 2123(II) (citing In re Gurley, 27 F.3d 551, 554 (Fed. Cir. 1994)). Thus, § 2123 focuses on the relationship between the applied reference and the claimed invention, not on the relationship between the applied reference and another applied reference on which an obviousness rejection is based. The section of the MPEP relied upon here by the Appellants is MPEP § 2145(X)(D)(2), titled "References Cannot Be Combined Where Reference Teaches Away from Their Combination." In this case, both Niznick and Haruyuki teach away from their combination for the reasons set forth above.

The Examiner also states that "the different dimensions [of Haruyuki and Niznick] alone do not make them incompatible." Ex. 2, page 5. But, the differences between the surface texture taught by Haruyuki and the surface texture taught by Niznick do not just relate to the dimensions

of the surface texture – they also relate to the surface texture itself. Niznick teaches that a surface texture with the peak-to-valley heights of 25 microns or greater should be created from an HA (hydroxyapatite) coating, TPS (titanium plasma spray) coating, or grit blasting, all of which introduce foreign matter to the underlying titanium implant surface. Ex. 7, column 7, lines 17-18, 47-48.

Haruyuki's surface does not add a material – it is based on etching the titanium material itself. Haruyuki knew about these types of material-adding processes that can increase the surface roughness. But, Haruyuki teaches the skilled artisan of the problems associated with these types of material-adding process, such as introducing “biotissue contamination” to the patient and/or operational complexity and high-cost. Ex. 5, page 3, column 1. As such, this is yet another direct contradiction between the Haruyuki and Niznick teachings on surface texture.

It is axiomatic that the entire teachings of the references must be considered when determining obviousness. When doing so here, the skilled artisan would never combine the teachings of Niznick with those of Haruyuki to produce Appellants' invention of claim 51. Prior art references simply cannot be combined where the references teach away from their combination. In re Grasselli, 713 F.2d at 743, (Fed. Cir. 1983); MPEP §§ 2143, 2145.

b. Niznick and Wennerberg Teach Away From Their Combination

In rejecting the present claims, the Examiner applied the portion of Wennerberg discussing the 3i Miniplant® implant system and the Nobelpharma implant system, both of which have machined – not acid-etched – surfaces. See Ex. 2, page 2, Ex. 6, page 624, Table 1. However, as discussed above, Niznick does not teach average peak-to-valley heights of an implant surface texture below 25 microns. Rather, Niznick teaches that the implant surface **must** be exceedingly **rough**, i.e., 25 microns or greater. See Ex. 7, column 7, lines 13-14.

Furthermore, as discussed above, Wennerberg, Niznick, and the combination thereof do not disclose, teach, or suggest a threaded portion having a roughened region having an acid etched surface produced after a native oxide layer has been removed from the threaded portion, as in the present claims. Why would one skilled in the art modify the smooth, machined surfaces of Wennerberg to add Niznick's surface having peak-to-valley heights greater than 25 microns?

Thus, the Appellants submit that the Wennerberg-Niznick combination fails for at least these reasons and the reasons provided above with respect to the Haruyuki-Niznick combination.

c. Niznick Teaches Away From The Invention of Claim 51

Claim 51 requires a smooth head portion and a threaded portion with a roughened region extending to the lowermost end, wherein the roughened region has an array of irregularities having peak-to-valley heights no greater than about 10 microns. This configuration is not disclosed in Niznick, and Niznick actually teaches away from it with his three-part surface roughness.

Niznick teaches that the implant's lowermost end at the self-tapping region 8 (Ex. 7, FIG. 1) or 21 (Ex. 7, FIG. 2) should be roughened up to a peak-to-valley height of 20 microns. Ex. 7, column 5, lines 16-20, column 7, lines 11-15, 41-45. Niznick considers this surface "relatively smooth" compared to the middle threaded region 14 (Ex. 7, column 7, lines 26), which has the peak-to-valley height of at least 25 microns brought about through a material-adding process, such as HA coating, TPS coating, or grit blasting. In fact, these extremely rough surfaces at the three distinct locations (i.e., (i) the distal end where the self-tapping feature resides, (ii) the proximal end at the top of the implant, and (iii) the middle region with the peak-to-valley heights of at least 25 microns) are the subject matter of Niznick's claim 1. As such, what Niznick

considered to be a “relatively smooth” surface is much rougher than the Appellants’ acid-etched surface.

Claim 51 requires a “smooth head portion” and a threaded portion with a roughened region being uniformly acid-etched and extending to the lowermost end. The roughened region has an array of irregularities having peak-to-valley heights no greater than about 10 microns. To make this rejection, the Examiner ignored the fundamental teaching of Niznick – the extremely rough surface of at least 25 microns (which is not, of course, uniformly acid-etched) – that teaches away from claim 51. A prior art reference that teaches away from the claimed invention is a significant factor to be considered in determining obviousness.

Because the proposed Haruyuki-Niznick and Wennerberg-Niznick combinations are improper for several reasons, the Appellants respectfully request the reversal of the rejections of claims 51, and 60-62, which are believed to be in a condition for allowance.

4. The Inventions of Claims 63-67 Are Not Obvious Over the Applied References

Independent claim 63 recites:

- a head portion having a smooth machined surface and for receiving a dental restoration component;
- a threaded portion including a self-tapping region adjacent to a lowermost end;
- the threaded portion having an acid-etched surface;
- the acid-etched surface extending to the lowermost end of the implant and within said self-tapping region; and
- the acid etched surface having an array of irregularities having peak-to-valley heights not greater than about 10 microns.

As noted above with respect to claims 51 and 60-62, the combinations of Haruyuki and Niznick and Wennerberg and Nuznick fail because:

- Haruyuki's surface is different from Appellants' surface and cannot be duplicated;
- Niznick is directly contradictory to Haruyuki with respect to the types of surface textures it teaches;
- the machined surfaces of the applied portion of Wennerberg are far different from Niznick's surfaces having peak-to-valley heights greater than 25 microns; and
- Niznick teaches away from several aspects of the claimed acid-etched surface.

Accordingly, for the reasons set forth above, claims 63-67 are not obvious over the applied references.

Additionally, independent claim 63 includes limitations regarding the self-tapping feature of the dental implant and, specifically, that the acid-etched surface with the array of irregularities is located within the self-tapping feature. Niznick, on the other hand, does not teach an acid-etched surface that extends along the threaded portion of the dental implant, into the self-tapping region, and to the lowermost end of the implant. Again, the middle threaded portion of Niznick's implant that is roughened does not extend to the lowermost end of the implant or into the self-tapping region. In fact, Niznick states:

For self-tapping insertion to be effective in dense bone, the cutting edges created by the grooves through the distal threads must be sharp enough to shave bone chips. Roughening the implant surface by grit-blasting, or by grit-blasting followed by coating the surface of the implant with a spray or molten titanium called Titanium Plasma Spray (TPS) or coating the surface with a bio-reactive material such as Hydroxylapatite (HA), rounds these cutting edges, decreasing the cutting efficiency of the self-tapping features.

Ex. 7, col. 1, ll. 53-62. Niznick also states:

The threaded distal end of the implant is preferably uncoated and has a smooth enough surface to maintain sharp cutting threads for self-tapping insertion, thereby shortening surgical time and improving initial stability.

Id. at col. 4, ll. 44-48. As such, Niznick not only does not suggest such a configuration of claims 63-67, but actually teaches away from it. Simply put, Niznick fails to overcome the deficiencies of Haruyuki and Wennerberg.

The Appellants respectfully request the reversal of the rejections of claims 63-67. Claims 63-67 are believed to be in a condition for allowance.

5. The Inventions of Claims 68-75 Are Not Obvious Over the Applied References

Independent claim 68 recites:

- a head portion having a non-rotational feature for engaging a dental restoration component;
- a threaded portion including a self-tapping region adjacent to a lowermost end;
- the threaded portion including a cylindrical section and a tapered section immediately adjacent to the lowermost end, the cylindrical section being longer than the tapered section;
- the threaded portion having an acid-etched surface;
- the acid etched surface extending from the lowermost end of the implant and into the cylindrical section of the threaded portion; and
- said acid etched surface having an array of irregularities having peak-to-valley heights not greater than about 10 microns.

As noted above with respect to claims 51 and 60-62, the combination of Haruyuki or Wennerberg and Niznick fails because:

- Haruyuki's surface is different from Appellants' surface and cannot be duplicated;
- Niznick is directly contradictory to Haruyuki with respect to the types of surface textures it teaches;
- the machined surfaces of the applied portion of Wennerberg are far different from Niznick's surfaces having peak-to-valley heights greater than 25 microns; and
- Niznick teaches away from several aspects of the claimed acid-etched surface.

Accordingly, for the reasons set forth above, claims 68-75 are not obvious over the applied references.

Claim 68 requires cylindrical and tapered sections and a self-tapping region within the tapered section. An acid-etched surface extends from the lowermost end, through the self-tapping region, and into the cylindrical section. The acid-etched surface has an array of irregularities having peak-to-valley heights no greater than about 10 microns. Niznick, on the other hand, does not teach an acid-etched surface extending from the lowermost end, through the self-tapping region, and into the cylindrical section. The middle threaded portion of Niznick's implant includes an extremely rough surface having peak-to-valley heights of greater than 25 microns. Of course, Niznick's roughened surface does not extend from the lowermost end of the implant, into the self-tapping region, and into the cylindrical section. Rather, Niznick desires smooth cutting edges. Namely, as discussed above with respect to claims 63-67, Niznick states:

For self-tapping insertion to be effective in dense bone, the cutting edges created by the grooves through the distal threads must be sharp enough to shave bone chips. Roughening the implant surface by grit-blasting, or by grit-blasting followed by coating the surface of the implant with a spray or molten titanium called Titanium Plasma Spray (TPS) or coating the surface with a bio-reactive material such as Hydroxylapatite (HA), rounds these cutting edges, decreasing the cutting efficiency of the self-tapping features.

Ex. 7, col. 1, ll. 53-62. Niznick also states:

The threaded distal end of the implant is preferably uncoated and has a smooth enough surface to maintain sharp cutting threads for self-tapping insertion, thereby shortening surgical time and improving initial stability.

Id. at col. 4, ll. 44-48. As such, Niznick not only does not suggest the configuration of claims 68-75, but actually teaches away from it.

The Appellants respectfully request the reversal of the rejections of claims 68-75.

6. The Applied References and Combination Thereof Do Not Result in the Inventions of Dependent Claims 61, 67, and 72

The Appellants contend that claims 61, 67, and 72 are separately patentable for the reason that not all of the elements of claims 61, 67, and 72 are taught in Haruyuki, Wennerberg, or Niznick. Specifically, each of these dependent claims recite that the second acid solution (which produces the acid-etched surface) is a mixture of sulfuric and hydrochloric acids. Haruyuki only discloses an HF and H₂O₂ solution. Haruyuki's two-step process differs from that of the Appellants' process and, more importantly, differs in the appearance of the resulting surfaces. Ex. 8, ¶¶ H, K, N. Therefore, the claims that recite the acids used in the Appellants' two-step treatment should be patentable over Haruyuki. And, neither Wennerberg nor Niznick provides any suggestion whatsoever that would lead one skilled in the art to utilize the inventions set forth in dependent claims 61, 67, and 72.

7. Dr. Porter's Declaration Establishes Secondary Evidence of Non-Obviousness

To overcome the obviousness rejections that were set forth by the Examiner, the Appellants previously submitted a Rule 132 Declaration from Dr. Porter (the "Porter Declaration") (Ex. 10) that sets forth evidence of nonobviousness. That Declaration was submitted by the Appellants on April 29, 2002.

The Porter Declaration establishes the nexus between the commercial Osseotite® surface and the claimed invention. The commercial Osseotite® surface is set forth in Exhibit A of the Porter Declaration (Ex. 10). Furthermore, several catalogs were included as Exhibit B, which show a myriad of examples of the overall screw-type structure of the dental implants that embody the Osseotite® surface. Without question, the dental implants with the Osseotite® surface that are discussed by Dr. Porter are covered by the pending claims that are the subject of this appeal.

Dr. Porter established a rapid increase in sales of implants having the Osseotite® surface relative to other implants. Ex. 10, page 2, ¶4, page 4, ¶7. He further establishes evidence of clinically-proven enhanced osseointegration due to the Osseotite® surface. Ex. 10, page 4, ¶6. Most importantly, Dr. Porter establishes that numerous competitive companies, in attempting to sell their dental implants, compare their surfaces with the Osseotite® surface. Ex. 10, page 5, ¶8. These “me-too” competitive products and their associated statements are competitive flattery indicating that the Osseotite® surface is the “gold standard” of implant surfaces.

In response to the Porter Declaration, the Examiner states that “the claimed product-by-process steps are quite broad such that they are not commensurate in scope with the process steps used to make Applicant’s samples”. Ex. 2, p. 6. That simply is not true. Dr. Porter’s Declaration discusses the Osseotite® surface in detail in paragraphs 3 and 5. Ex. 10, page 4, ¶3, page 5, ¶5. That language tracks the language of the claims. And, Dr. Porter discloses the structure of these implants in the catalogs that are included in Exhibit B. Ex. 10, Ex. B.

In summary, the Porter Declaration is yet another reason that the pending claims are not obvious.

VIII. CLAIMS APPENDIX

A clean copy of the pending claims 51 and 60-75 involved in the appeal is included in the Claims Appendix.

IX. EVIDENCE APPENDIX

A copy of the evidence relied upon by Appellant is included in the Evidence Appendix and is herein referenced. A list of evidence and where each was entered in the record is included in the Index to the Appendices.

X. RELATED PROCEEDINGS APPENDIX

As there are no related proceedings, no information is provided in the Related Proceedings Appendix.

XI. CONCLUSION

Appellant respectfully submits that the Examiner's rejections fail to present a prima facie case of obviousness under 35 U.S.C. § 103. Based upon the arguments submitted above, the Appellant respectfully solicits the reversal of the Examiner's 35 U.S.C. § 103 rejections of claims 51 and 60-75 on at least the grounds noted above.

It is believed that no fees are due; however, should any additional fees be required (except for payment of the issue fee), the Commissioner is authorized to deduct the fees from Nixon Peabody Deposit Account No. 50-4181, Order No. 247168-000035USC1.

Respectfully submitted,

Date: May 26, 2009

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CLAIMS APPENDIX

CLEAN COPY OF CLAIMS ON APPEAL

51. A dental implant made of titanium metal, comprising:
a smooth head portion for receiving a dental restoration component;
a lowermost end opposing said head portion;
a threaded portion for engaging bone between said head portion and said lowermost end; and
a roughened region for facilitating osseointegration with said bone located on said threaded portion and extending to said lowermost end of said implant, said roughened region being uniformly acid etched with a second acid solution after a native oxide layer had been removed by contact with a first acid solution with minimum consumption of said titanium metal, said roughened region including an array of irregularities having peak-to-valley heights not greater than about 10 microns.
60. A titanium metal dental implant of Claim 51, wherein said first acid solution is aqueous hydrofluoric acid.
61. A titanium metal dental implant of Claim 51, wherein said second acid solution is a mixture of sulfuric and hydrochloric acids.
62. A titanium metal dental implant of Claim 51, wherein said irregularities include cone-shaped elements.
63. A titanium dental implant, comprising:
a head portion for receiving a dental restoration component, said head portion including a non-rotational feature for engaging said dental restoration component, said head portion having a smooth machined surface;
a lowermost end opposing said head portion; and
a threaded portion having continuous thread turns and being located between said head portion and said lowermost end, said threaded portion including a self-tapping region

adjacent to said lowermost end, said threaded portion having an acid-etched surface for facilitating osseointegration with said bone, said acid-etched surface extending to said lowermost end of said implant and within said self-tapping region, said acid-etched surface being produced on said threaded portion after a native oxide layer has been removed from said threaded surface, said acid-etched surface having an array of irregularities having peak-to-valley heights not greater than about 10 microns, said irregularities including cone-shaped elements.

64. The implant of claim 63, said acid-etched surface is located on said threaded portion below the first uppermost turn of said threaded portion.
65. The implant of claim 63, wherein said native oxide is removed by a first acid solution after which the resulting surface is etched with a second acid solution to create said acid-etched surface.
66. The implant of claim 65, said first acid solution is aqueous hydrofluoric acid.
67. The implant of claim 66, wherein said second acid solution is a mixture of sulfuric and hydrochloric acids.
68. A titanium dental implant, comprising:
a head portion for receiving a dental restoration component, said head portion including a non-rotational feature for engaging said dental restoration component;
a lowermost end opposing said head portion; and
a threaded portion having continuous thread turns and being located between said head portion and said lowermost end, said threaded portion including a cylindrical section and a tapered section immediately adjacent to said lowermost end, said cylindrical section being longer than said tapered section, said tapered section including a self-tapping region that extends to said lowermost end, said threaded portion having an acid-etched surface for facilitating osseointegration with said bone, said acid-etched surface extending from said lowermost end and into said cylindrical section of said threaded portion, said acid-etched surface being produced on said threaded portion

after a native oxide layer has been removed from said threaded portion, said acid-etched surface having an array of irregularities having peak-to-valley heights not greater than about 10 microns, said irregularities including cone-shaped elements.

69. The implant of claim 68, said acid-etched surface extends from said lowermost end to at least an uppermost turn of said threaded portion.

70. The implant of claim 68, wherein said native oxide is removed by a first acid solution after which the resulting surface is etched with a second acid solution.

71. The implant of claim 70, said first acid solution is aqueous hydrofluoric acid.

72. The implant of claim 70, wherein said second acid solution is a mixture of sulfuric and hydrochloric acids.

73. The implant of claim 68, further including a neck portion between said head portion and said threaded portion.

74. The implant of claim 73, wherein said neck portion is a smooth machined surface, said head portion having a smooth machined surface.

75. The implant of claim 68, wherein said head portion has a smooth machined surface.

EVIDENCE APPENDIX

RELATED PROCEEDINGS APPENDIX

None. There are no related proceedings.

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